

REMARKS

Formal Matters

Claims 1-5, 17, 19-21, 84-85 and 90 are pending in the instant application. In view of the following remarks, Applicants respectfully request reconsideration of Claims 1-5, 17, 19-21, 84-85 and 90, the only claims under examination in the instant application.

Claim Rejections- 35 U.S.C. § 101

In the Office Action dated June 24, 2009, the Examiner rejected Claims 1-5, 17, 19-21, 84-85 and 90 as allegedly failing to comply to requirements set forth under 35 USC § 101, citing *In re Bilski*. In making the rejection, in the Examiner's remarks to the claims as presented in a Response filed November 25, 2008, it was stated (underline and italics added for emphasis):

"Applicant's (sic) arguments are not found persuasive as a processing component and data analysis component do not define or recite any specific structure for which to tie the claims. In other words, the components could read on performing the steps mentally wherein the processing and data analysis components read on the human mind."

The Applicants assert that two issues are presented in the reasoning presented in the Action, based the M.P.E.P. § 2111 (underline and italics added for emphasis):

"The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004)"

The first clause in the claims as presented on November 25, 2008, states (underline and italics added for emphasis):

"providing a system comprising a sample processing component and a data analysis component;"

First, it is inferred in the instruction from the M.P.E.P. cited above, as well as other sections of the M.P.E.P., that all the words in a claim must be considered. It appears from the Action that the Examiner seems to have ignored the term "system". Further, the Examiner has clearly failed to give the claims their broadest reasonable construction in light of the specification.

Had the instruction under M.P.E.P. § 2111 been adhered to, it would have been evident that the specification of the instant application has significant support for construing "system", as well as "sample processing component" and "data analysis component" in a fashion consistent with the machine test as recited in the Action on page 3.

Accordingly, the Applicants request that the rejection of the claims under 35 USC § 101 be withdrawn.

Claim Rejections- 35 U.S.C. § 103(a)

In the Action, the Examiner rejected Claims 1-5, 17, 19-21, 84-85 and 90 of the instant application under 35 U.S.C. § 103(a) as allegedly obvious over Ranade et al. (*Gen. Res.* **2009** *11*, 1261-1268; hereafter Ranade) in view of Liu, et al. (US 6,920,398; hereafter Liu).

It is stated in the M.P.E.P. § 2143.03 that (underline and italics added for emphasis):

"All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)

The Applicants respectfully submit that the asserted combination of Ranade and Liu fails to render various claimed embodiments of a method and system for genotyping of the instant application *prima facie* obvious. The reason that the asserted combination does not present a *prima facie* case of obviousness stems from the mischaracterization of the cited art, as well as the failure of the Examiner to carefully consider all words in various claimed embodiments of the instant application as it would be interpreted by one of ordinary skill in the art to which said subject matter pertains [see 35 USC 103(a)]. Accordingly, a careful analysis of the teachings of Ranade and Liu would lead one of ordinary skill in the bioinformatics arts to conclude that the asserted combination as a whole would not render various claimed embodiments of a method and system for genotyping of the instant application *prima facie* obvious.

For example, but not limited by, in the Action, it is asserted that Ranade teaches generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within the bounds of a particular data cluster. In support of this assertion, the Examiner cites Ranade as teaching a probability that a particular sample falls within a genotype class, and that this infers the teaching of a likelihood model.

First, the Applicants aver that this is a serious mischaracterization of Ranade. One of ordinary skill in the art of bioinformatics would readily understand that Ranade teaches using a k-

means clustering algorithm based on nearest-centroid sorting for determining the genotype of a sample (see Ranade, bottom pg. 1263-top pg.1264) and not various embodiments of a method and system for genotyping utilizing a likelihood model. Additionally, one of ordinary skill in the art of bioinformatics would recognize the word "probability" cherry-picked out of the teachings of Ranade relates to the assignment of a quality score for the nearest-centroid-based k-means cluster determination of a genotype to a sample (see Ranade, pg. 1265). The Applicants submit that one of ordinary skill in the bioinformatics arts would recognize that assigning a quality score to a determination of a genotype has nothing to do with a specific step of determining a genotype for a sample.

In summary, Ranade teaches the use of a k-means clustering algorithm based on nearest-centroid sorting for determining a genotype of a sample, and further teaches assigning a quality value to that determination using a bivariate normal probability distribution. Accordingly, Ranade is devoid of any teaching relating to various embodiments of claimed methods and systems of the instant application utilizing a likelihood model. Such methods and systems are found only in the instant application, and not in Ranade.

Further, the Applicants assert that Liu does not make up the deficiency of Ranade. For example, but not limited by, there are no teachings in Liu for various embodiments of methods and systems of genotype clustering that utilize a likelihood model for genotype clustering based upon the intensity information of a selected sample. As recited in the instructions of the M.P.E.P § 2143.03, every word in a claim must be carefully considered.

Accordingly, as both Ranade and Liu fail to teach various embodiments of methods and systems of the instant application utilizing a likelihood model, then the asserted combination fails to teach various embodiments of what is claimed in the instant application. As such, no *prima facie* case of obviousness has been asserted. Therefore, the Applicants request that the rejection be withdrawn.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this case, the Examiner is invited to contact the Applicants' agent at the telephone number listed below.

Fee Authorization

In addition to the fees for the filing of a Request for Continued Examination, the fee for a three month extension is also included with this response. Should any additional fee be necessary for the timely submission of this paper, the Commissioner is hereby authorized to charge **Deposit Account No. 50-3994 (order no. 4908US)**. Any deficiency or overpayment should be charged or credited to this deposit account.

Respectfully submitted,

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